INTERNATIONAL STANDARD

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Medical devices — Quality management — Medical device nomenclature data structure

Dispositifs médicaux — Management de la qualité — Structure des données de nomenclature des dispositifs médicaux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15225 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO 15225:2000), which has been technically revised. It also incorporates the Amendment ISO 15225:2000/Amd.1:2004.

Introduction

This International Standard is intended to assist competent authorities, conformity assessment bodies, healthcare providers and manufacturers in the submission and exchange of information. It is intended that the information covered by this International Standard be available in the public domain.

This second edition of this International Standard is based on experience gained from utilization of the first edition. The following major changes have been made to the first edition:

— definitions have been added in Clause 3 for base concept, collective term, device category, device type, generic device group, Global Medical Device Nomenclature (GMDN), GMDN agency, multiple-linked synonym, product specifier and template specifier;

— Codes 13, 14 and 15 have been added in Annex A, and the descriptions have been updated with examples of new technologies;

— Annex D has been added containing examples of collective terms.

The requirements contained in this International Standard are applicable to the development and updating of an international nomenclature and have been prepared specifically for construction of the Global Medical Device Nomenclature (GMDN).

Medical devices — Quality management — Medical device nomenclature data structure

1 Scope

This International Standard provides rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, health care providers and end users.

This International Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases that utilize the nomenclature system described herein.

The requirements contained in this International Standard are applicable to the development and maintenance of an international nomenclature for medical device identification.

This International Standard does not include the nomenclature itself, which is provided as a data file.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 8859-1:1998, *Information technology — 8-bit single-byte coded graphic character sets — Part 1: Latin alphabet No. 1*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply[1)].

3.1
base concept
broadest representation of the generic device group, and the primary listing basis of the GMDN

[GMDN Agency]

3.2
character
member of a set of elements used for the organization, control or representation of data

[ISO/IEC 8859-1:1998, definition 4.3]

1) In this International Standard, many terms are used which have their basis in regulatory statutes, e.g. “medical device”, “custom made medical device” and “manufacturer”. These terms are defined in the respective jurisdictions where the nomenclature are used.

3.3
code
system of alpha, alphanumeric or numeric characters and rules by which information is represented, communicated, or both

3.4
collective term
term used to describe broad common features or characteristics within which a number of generic device group terms are recognized, for regulatory or other purposes

NOTE Generic devices can be linked to one or more collective terms to indicate, for example, the following:

— common areas of intended use;

— the application of common technology;

— the use of specific hazardous or difficult materials;

— the application of a particular medical speciality;

— the need for application of specific manufacturing processes;

— the presence of other common attributes with which to identify certain devices;

— the common descriptor of a broad device concept (i.e. a template term).

3.5
concept
unit of knowledge created by a unique combination of characteristics

[ISO 1087-1:2000, definition 3.2.1]

3.6
definition
formal concise statement of the meaning of a preferred term or template term

3.7
device category
broadest grouping within the nomenclature

3.8
device intended for clinical investigation
device intended for use in a designed and planned systematic study in or on human subjects to verify the safety, performance, or both

3.9
device intended for performance evaluation
device intended by the manufacturer to be subject to performance evaluation studies in laboratories for medical analyses or other appropriate environments outside the manufacturer's premises

3.10
device type
identification of a manufacturer's specific product

NOTE The manufacturer's specific product is the make and model.

3.11
file
named set of records stored or processed as a unit

[ISO/IEC 2382-1:1993, definition 01.08.06]

3.12
foreign key
⟨relation⟩ one or a group of attributes that corresponds to a primary key in another relation

[ISO/IEC 2382-17:1999, definition 17.04.15]

3.13
generic device group
set of devices having the same or similar intended use, common technology, or both

3.14
Global Medical Device Nomenclature
GMDN
nomenclature based on the structure of this International Standard, which provides information in the form of a code to indicate the generic descriptor within which a device type can be identified

NOTE By reference to this globally accepted, generic medical device nomenclature, other particular devices which have substantially similar generic features but which come from another source can be identified, for reasons of data exchange between competent authorities and others, for the exchange of post-market vigilance information and for inventory purposes.

3.15
GMDN agency
organization representing the interests of regulatory agencies, manufacturers and healthcare providers to ensure the continued relevance and effectiveness of the GMDN, and is responsible for the development, control and distribution of the GMDN

3.16
identifier
⟨organization of data⟩ one or more characters used to identify or name a data element and possibly to indicate certain properties of that data element

[ISO/IEC 2382-4:1999, definition 04.09.02]

3.17
multiple-linked synonym
alternative name(s) for a synonym term linked to more than one preferred or template term

[GMDN Agency]

3.18
name
verbal designation of an individual concept

NOTE Adapted from ISO 1087-1:2000, definition 3.4.2.

3.19
nomenclature
terminology structured systematically according to pre-established naming rules

[ISO 1087-1:2000, definition 3.5.3]

3.20
preferred term
name established to describe a device, or devices, having the same or similar intended use or commonality of technology

3.21
primary key
a key that identifies one record

[ISO/IEC 2382-17:1999, definition 17.03.11]

3.22
product specifier
marker to indicate which terms can and cannot be used for product identification

[GMDN Agency]

3.23
relational structure
data structure in which the data are arranged as relations

[ISO/IEC 2382-17:1999, definition 17.04.03]

3.24
secondary key
a key that is not a primary key, but for which an index is maintained and that may denote more than one record

[ISO/IEC 2382-17:1999, definition 17.03.12]

3.25
synonym
alternative name for a preferred or template term

3.26
template specifier
data field which is set to indicate that the term is a template term and, at the same time, which specifies that the first characters from the term field are used to look up the preferred terms that start with the same characters

3.27
template term
term used to create a simple hierarchy for preferred terms

3.28
term
verbal designation of a general concept in a specific subject field

NOTE Adapted from ISO 1087-1:2000, definition 3.4.3.

4 Principle of structure

4.1 General

The nomenclature is structured in four stages. These stages differ in the breadth of the sets of devices represented by the terms defined within each stage. All medical devices can be classified within each stage. The stages have a relational structure in the following order:

a) device category (see 4.2);

b) collective term (see 4.3);

c) generic device group (see 4.4);

d) device type (see 4.5).

4.2 Device category

Individual categories have broad usage definitions representing disparate devices that have common areas of intended use or common technology. Device category has the largest number of devices covered by each term.

For data organization, device category includes the record holding a device category term and associated data, such as its code and other attributes.

4.3 Collective term

Collective terms are terms used in the nomenclature for:

a) grouping together preferred terms with common characteristics, e.g. common technology, materials, medical specialties, manufacturing processes;

NOTE Collective terms can replace or support template terms.

b) illustrating the scope of certificates issued by certification bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system;

c) identifying the range of skills and general technological abilities for which a notified body has been approved, and is so appointed by the relevant regulatory authority;

d) exchanging of information between regulatory authorities when general information on individual manufacturers capabilities is notified for inclusion within data-exchange systems.

Collective terms are linked directly to preferred terms.

4.4 Generic device group

A generic device group contains sets of devices having the same or similar intended uses or commonality of technology. Sets of devices are grouped together for the purpose of device vigilance reporting, or other purposes where sets of essentially similar devices from different sources need to be collected. Potentially, any device attribute (e.g. implant/non-implant, sterile/non-sterile) can be used as a means of arranging associated data.

For data organization, the generic device group includes the record holding a device group term. The device group term can include the following:

a) preferred term (see 5.2.3);

b) template term (see 5.2.4);

c) synonym (see 5.2.5);

d) multiple-linked synonym (see 5.2.6).

It can also include associated data, as follows:

— code;

— definition;

— for synonyms or multiple-linked synonyms, code of the generic device group record holding the preferred term or template term;

— for templates, the template specifier.

4.5 Device type

A device type contains individual medical devices including devices intended for clinical investigation, devices intended for performance evaluation and custom-made devices or sets of medical devices including variants which may be produced. Device types contain sufficient characteristics in common for the manufacturer to establish a make and model.

For data organization, device type includes the record holding the device type designation and its associated data, such as its code and other attributes.

Names to be stored are drawn from the manufacturer's documentation.

4.6 Nomenclature structure example

Table 1 is an example of the nomenclature structure.

Table 1 — Example of GMDN structure linked to an alignment rod

Device categories:	03 Dental devices 09 Reusable devices
Links to - -	
Collective terms:	
	CT465 Cranial surgery
	CT146 Dentistry
	CT317 Infant/paediatric
	CT321 Long-term surgical invasive
	CT326 Manually powered/operated
	CT177 Metals
	CT328 Natural orifice
	CT166 Oral surgical fixation/distraction and ancillary
	CT152 Paediatrics
	CT982 Reusable
	CT335 Single purpose
	CT334 Single-patient use
	CT337 Sterilizable
	CT233 Surgery
Links to - -	
Generic device group:	GMDN code:47677 Term: Craniofacial alignment rod Definition: A surgical instrument typically used in pairs to facilitate correct cranial orientation of craniofacial implants (e.g., fixation plates being attached to jaw bones) and other devices (e.g. craniofacial distractors) during their application in craniofacial surgery. It is typically designed as a long, thin, rigid rod made of high-grade stainless steel or titanium alloy with connectors at either end for attachment to the devices being aligned; it may have a knurled mid section (to provide better grip) onto which other instruments can be locked to assist the orientation procedure. This is a reusable device.
Links to - -	
Device type:	Make: Acme Model: 298FK3Z Trade name: Alignment rod

5 Requirements

5.1 Device category

Device categories are managed by the GMDN agency and are part of the data file.

The list is not exhaustive, other device categories may be added (see Annex A).

5.2 Generic device group

5.2.1 General

Generic device groups are managed by the GMDN agency and are part of the data file.

For the generation of generic device group terms, see Annex B.

A generic device group can be a member of more than one device category.

The nomenclature shall consist of preferred terms, template terms, synonyms and multiple-linked synonyms. All terms should be given in the singular form.

5.2.2 Abbreviations and acronyms

Abbreviations and acronyms can be used to create generic device group names.

Any abbreviation being adopted should use widely recognized terminology.

5.2.3 Preferred term

A preferred term represents a device type or a set of device types that perform similar or equivalent functions or have technical characteristics in common.

A preferred term is the only term that can be used for product identification.

A preferred term shall be unambiguous and comprise the following:

a) base concept;

b) (if appropriate) one or more qualifiers following the base concept, and which are separated from the base concept by a comma;

c) a comma and one space to delimit each qualifier.

EXAMPLE Brachytherapy system applicator, remote afterloading, bladder.

More specific classification can be achieved by addition of further qualifiers.

The base concept shall be the primary listing basis.

Unambiguous qualifiers shall be used.

Ambiguous qualifiers include phrases such as “sundries”, “others”, “appliances”, “miscellaneous” and “various”.

Trade names shall not be used as preferred terms.

Preferred terms shall be assigned a definition of not more than 700 characters.

5.2.4 Template terms

A template term is used when more than two preferred terms are formed using the same base concept.

The template term shall be formed from the common base concept followed by the qualifier <specify>.

A template term functions only as a navigational term within the nomenclature. Its permanency cannot be guaranteed due to preferred term development.

Template terms cannot be used for product identification.

Template terms shall not be used as synonyms.

Template terms shall be assigned a definition of not more than 700 characters.

5.2.5 Synonyms

Synonyms shall be linked to only one preferred term or to one template term, whichever is appropriate.

Synonyms are an aid to locating the appropriate preferred term.

Synonym terms cannot be used for product identification.

Synonyms shall not be linked to other synonyms.

5.2.6 Multiple-linked synonyms

A multiple-linked synonym is a term that is typically of a higher order, and can therefore be linked to more than one preferred term, or template term, or preferred term and template term.

EXAMPLE 1 Higher order terms

EDMA term: **Thyroid Function Hormones**

GMDN related terms: **Triiodothyronine uptake kit**

Thyroxine kit

Triiodothyronine kit

Free triiodothyronine kit

Free thyroxine kit.

EXAMPLE 2 Combination product terms

UMDNS term: **Reagents, Staphylococcus/Streptococcus Detection**

GMDN related terms: **Staphylococcus kit**

Streptococcus antibody kit

Streptococcus antigen kit.

A multiple-linked synonym shall have the same construction format and status as a synonym term.

Multiple-linked synonym terms may not be used for the purpose of product identification.

5.3 Device type

Device types are used to identify a manufacturer's specific product (i.e. make and model) and are managed by, or on behalf of, the device manufacturer.

A device type shall not be linked to more than one preferred term.

Device types shall be designated under the code of a preferred term, in accordance with the primary intended uses specified by the manufacturer.

5.4 Collective term

Collective terms shall group several preferred terms with common features (see 4.3). Collective terms are managed by the GMDN Agency and are part of the data file.

See Annex D.

6 Data file dictionary

6.1 General

This clause is provided for information system designers implementing the nomenclature within a database. It provides the minimum requirements for the data fields needed to hold the nomenclature system. Each stage in the data structure is represented by a data file for which the requirements of 6.2 to 6.5 apply.

Further data fields may be added to all data files depending on the requirements of the end user of the database system in question.

The character set for transmissions shall be the Latin alphabet No. 1 as specified in ISO/IEC 8859-1.

6.2 Device category data file

The minimum number of fields shall be as specified in Table 2.

The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

See Annex A for examples.

When information is exchanged and records in the data files described in Table 2 are part of this information, then only the code of the relevant records needs to be transmitted.

Table 2 — Requirements for device category data file

Identifier	Data category and format	Comments
Code	Numeric, two digits	Primary key
Term	Alphanumeric, 60 characters	Primary key
Definition	Alphanumeric, 1 260 characters	—

6.3 Generic device group data file

The data field code shall be assigned an incremental sequential cardinal number starting from the value 10 000. After a new record is added to the data file, the code shall be incremented by one (1).

The generic device group data file shall be as specified in Table 3.

Table 3 — Requirements for generic device group data file

Identifier	Data category and format	Comments
Code	Numeric, five digits	Primary key
Term	Alphanumeric, 120 characters	Primary key
Synonym code	Numeric, five digits	If not equal to zero (nil) then this device group is a synonym where the numeric value is the code of the preferred term or template.
Template specifier	Numeric, two digits	If not equal to zero (nil) then this device group is a template. The numeric value represents how many characters from the term are to be used for looking up (listing) the matching preferred term base concept.
Definition	Alphanumeric, max 700 characters	See also 5.2.
Product specifier	Alpha, 30 characters	The text “product identifier” or “not for product identification” is linked to all terms to make it clear to the nomenclature user which terms are allowed for product identification and which are not.
NOTE Annex C gives examples of device group records.		

The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

There is no foreign key in this data file relating it to the device category data file, since there is a many-to-many relation between these two data files. The system designer should apply the method(s) available in the database tool in order to achieve this many-to-many relation, the most common method being a data file holding as foreign keys the codes of both the device category and generic device group records.

The code of the generic device group’s records, where the synonym code or the template specifier is not zero (nil), shall not be used as a foreign key in related data files.

These records may not be available in all natural language versions of the nomenclature system and in such cases no relation will exist (see Annex C).

Generic device group codes in the range 1 to 9999 cannot be used in data transmissions that comply with this International Standard. This demands that an official list of generic device groups will never contain records having these code values. Generic device group codes in the range 1 to 9999 are exclusively reserved for assignment by the end user. These codes are made available for the convenience of end users to store terms outside the scope of this International Standard.

6.4 Device type data file

The minimum number of fields shall be as specified in Table 4.

Table 4 — Requirements for device type data file

Identifier	Data category and format	Comments
Generic device group code	Numeric, five digits	Foreign key, represents the link to a generic device group record (preferred term in the nomenclature)
Make	Alphanumeric, 60 characters	Secondary key, can also act as a foreign key
Model	Alphanumeric, 60 characters	The make and model represents, when concatenated, the primary key

When concatenated (see Table 4) the contents of the data fields “make” and “model” shall be unique.

The data field “make” is used to identify the manufacturer on the device label. When appropriate, the authorized representative may be identified. A shortened version, such as an easily recognizable trade name or alpha-numeric trade mark, may be used.

The data field model should be the name used by the manufacturer to identify the particular type of device. In appropriate circumstances, other informative formats, such as brand or bar code data, may be used. This data field should not be confused with the serial number or lot number assigned to the individual device or lots of devices.

The reasoning for having two data fields representing the primary key is that the model name used by one manufacturer (or even by the same manufacturer when he uses several makes to represent his name) could possibly be used by other manufacturers, thus making it unsuitable for use as a primary key.

The system designer may find it useful to assign a single (numeric) data field as a more manageable primary key in the database system for this data file.

Each device type record should be supported by a unique code for data transmission.

If it is considered of value to include device risk class data, this should be limited to links at the device type. Risk classification at the generic device group level is not considered in this International Standard.

6.5 Collective term data file

The minimum number of identifiers shall be as specified in Table 5.

Table 5 — Requirements for collective term data file

Identifier	Data category and format (maximum)	Comments
Code	Alphanumeric, six characters	Primary key
Term	Alphanumeric, 150 characters	Primary key
Definition	Alpha, 300 characters	—

The collective term code consists of two alpha characters, followed by up to four numeric characters.

EXAMPLE CT1234.

Annex A
(informative)

Device categories

This annex provides descriptions and examples of device categories.

— **Code: 01**

Term: Active implantable devices

Devices that operate with an integral power source (i.e. independent of energy from the human body or gravity), that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain temporarily or permanently.

EXAMPLE 1 Cochlear implants, implantable defibrillators, implantable infusion pumps, implantable stimulators, pacemakers, and their accessories.

— **Code: 02**

Term: Anaesthetic and respiratory devices

Devices used to supply, condition, monitor, dispense or deliver respiratory or anaesthetic gases, vapours or other substances, in order to provide or control respiration or anaesthesia.

EXAMPLE 2 Airways, anaesthesia systems, breathing circuits, humidifiers, tracheal tubes, ventilators, and their accessories.

— **Code: 03**

Term: Dental devices

Devices used to diagnose, prevent, monitor, treat or alleviate oral, maxillo-facial and dental disease/disorders.

EXAMPLE 3 Dental amalgam, dental cements, dental hand instruments, dental implants, dental materials, dental tools/laboratory devices, and their accessories.

— **Code: 04**

Term: Electro mechanical medical devices

Devices that operate on electrical energy (electromedical) or through some integrated physical mechanism or machinery (mechanical).

EXAMPLE 4 Specialized beds, defibrillators, dialysis systems, electrocardiographs (ECG), electroencephalographs (EEG), endoscopes, infusion pumps, lasers, operation/examination tables/lights, suction systems, and their accessories.

— **Code: 05**

Term: Hospital hardware

Devices that typically do not directly or actively participate in the diagnosis or treatment of patients, but that support or facilitate such activities.

EXAMPLE 5 Air cleaners, baths, detergents, disinfectants, floor coverings/mats, incinerators, patient beds, patient transfer equipment, sterilizers, and their accessories.

— **Code: 06**

Term: *In vitro* diagnostic devices

Devices used to examine clinical samples taken from the human body to evaluate physiological or pathological conditions.

EXAMPLE 6 Analysers, blood glucose monitoring devices, *in vitro* diagnostic (IVD) test kits/calibrators/controls, dedicated laboratory equipment, microbial sensitivity systems, and their accessories.

— **Code: 07**

Term: Non-active implantable devices

Devices without an integral power source that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain for longer than 30 days.

EXAMPLE 7 Cardiovascular clips, embolization implants, orthopaedic fixation systems, intrauterine devices, heart valves, bone prostheses, and their accessories.

— **Code: 08**

Term: Ophthalmic and optical devices

Devices used to diagnose, prevent, monitor, treat, correct or alleviate diseases or disorders related to the eye.

EXAMPLE 8 Contact lenses, keratomes, intraocular lenses, slit lamps, ophthalmic test instruments, phacoemulsification systems, tonometers, and their accessories.

— **Code: 09**

Term: Reusable devices

Devices that can be used for more than one application period, often involving cleaning or sterilization between the periods.

EXAMPLE 9 Drills, elastic bandages, haemostats, medicine administration kits, saws, scar management garments, reusable surgical instruments (chisels, scissors, retractors, scalpels), and their accessories.

— **Code: 10**

Term: Single-use devices

Device that is intended for one use, or on a single patient during a single procedure.

EXAMPLE 10 Adhesive tapes, bandages, blood collection devices, catheters, condoms, dressings, electrodes, kits/sets (biopsy, intravenous infusion), needles, single-use surgical instruments/products (cannulae, scalpels, absorbents), and their accessories.

— **Code: 11**

Term: Assistive products for persons with disability

Devices specially produced or adapted which compensate for, relieve, prevent or neutralize an impairment, disability or handicap.

EXAMPLE 11 Artificial limbs, audiometers, crutches, hearing aids, lifts, orientation aids, rehabilitation devices, wheelchairs, and their accessories.

— **Code: 12**

Term: Diagnostic and therapeutic radiation devices

Devices that use radiation energy, including *in vivo* isotopes, excited particle energy, magnetic resonance imaging, nuclear energy, ultrasound and x-ray, for the purpose of providing diagnostic imaging or therapeutic radiation treatment.

EXAMPLE 12 Accelerator systems, bone absorptiometric systems, accelerator systems, computed tomography (CT) systems, magnetic resonance imaging (MRI) systems, positron emission tomography (PET) system, X-ray systems, and their accessories.

NOTE Radiant warming devices are excluded.

— **Code: 13**

Term: Complementary therapy devices

Devices that use traditional or alternative methods to diagnose or treat illness. These devices may be used alone or to complement allopathic medicine; their use is commonly related to the body's innate energy system.

EXAMPLE 13 Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups.

— **Code: 14**

Term: Biological derived devices

Devices incorporating human or animal tissues, or tissue derived products.

EXAMPLE 14 Heart valves, tissue growth products.

— **Code: 15**

Term: Healthcare facility products and adaptations

Building-related products and furnishings for the function and utilization of healthcare facilities, or for home healthcare, which are not involved in patient diagnosis or disease-related treatment.

EXAMPLE 15 Electrical outlets, safety systems (e.g. electrical fail-safe systems, personnel assistance warning systems), fixed generators, sanitation products (e.g. special toilets and baths for routine hygiene), permanent floor/wall coverings, goods transportation systems, adapted and standard furniture, and their accessories.

Annex B
(informative)

Examples for generation of generic device group terms and synonyms

B.1 General

This annex provides examples for the purpose of generating generic device group terms and updating the nomenclature.

The terms used in the examples provided are for illustrative purposes.

B.2 Structure of generic device group terms

The preferred term should be of such a character that the nomenclature acquires a functional architecture, bearing in mind the users and use of the device. The qualifier, especially when common to many terms, may be based on the properties, characteristics or field of use of the devices, by using well-established conventions when appropriate.

The general structure of the preferred term is the base concept (singular noun or noun phrase), followed by one or more qualifiers (adjectives or adjectival phrases), delimited or separated by a comma. The base concept is the broadest representation of the generic device group of medical devices that is further described by the qualifiers. The qualifiers, moving from left to right, should be ordered from broader (less specific) to narrower (more specific).

B.3 Examples of generic device group terms

B.3.1 A preferred term should be constructed in the following manner:

Base concept	qualifier	qualifier
Noun or noun phrase	adjective or adjectival phrase	adjective or adjectival phrase

B.3.2 The following are examples of preferred terms structured by base concept followed by qualifier.

EXAMPLE 1 Suture, nylon.

EXAMPLE 2 Suture, polyethylene.

EXAMPLE 3 Suture, polyglyconate.

B.3.3 The following are examples of preferred terms using a qualifier which reflects the “field of use” of the devices to be named by the term.

EXAMPLE 1 Haemofiltration system.

EXAMPLE 2 Peritoneal dialysis system.

EXAMPLE 3 Haemodialysis system.

EXAMPLE 4 Haemodialysis system air bubble/foam guard.

EXAMPLE 5 Haemodialysis system bicarbonate mixer.

B.3.4 Where there are more than two preferred terms with the same base concept, a template may be introduced.

EXAMPLE 1 Audiometer, <specify>.

EXAMPLE 2 Audiometer, auditory evoked response.

EXAMPLE 3 Audiometer, automatic-recording.

EXAMPLE 4 Audiometer, computer-controlled.

B.3.5 The following are examples of synonyms:

EXAMPLE 1	Dinamap	"linked to"	Sphygmomanometer, electronic, <specify>
EXAMPLE 2	AED (automatic external defibrillator)	"linked to"	Defibrillator, automatic
EXAMPLE 3	Ambu bag	"linked to"	Resuscitator, pulmonary, <specify>

B.3.6 Any definition should be written in a manner that makes it comprehensible to all nomenclature users.

EXAMPLE 1 Audiometer, <specify>

An electroacoustic device designed for the measurement of hearing, most commonly for measuring the hearing threshold level. It uses controlled levels of test tones and signals to conduct diagnostic hearing evaluations and assist in the diagnosis of possible otological disorders.

EXAMPLE 2 Audiometer, automatic, computer-controlled

An electroacoustic device designed to measure the hearing threshold of a patient by presenting tones of increasing or decreasing intensity through headphones to establish the level at which the patient first becomes aware of the sounds. A computer or microprocessor in the device automatically produces tones that sweep the audiometric scale and controls tone intensity and frequency. The device also records the patient's responses and may display calculated hearing thresholds. This device may have the capacity to present a fixed frequency or a steadily changing frequency. It may also provide both continuous and pulsed tone outputs.

B.4 Abbreviations

The following are examples of abbreviations used in, or as part of, a synonym:

EXAMPLE 1 AARK (automated anaesthesia record keeper).

EXAMPLE 2 CPAP unit (continuous positive airway pressure unit).

B.5 Example of style

B.5.1 The first letter of a device category term or a generic device group term should be in upper case (capital letters). Thereafter, all letters should be reproduced in lower case (small letters).

EXAMPLE 1 Capitalized first letter of the base concept: Defibrillator

EXAMPLE 2 Capitalized first letter of the base concept followed by a qualifier in small letters: Microscope, general-purpose